

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND
COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION,

MDL No.: 2419

Dkt No. 1:13-MD-02419 (RWZ)

THIS DOCUMENT RELATES TO:

Suits Naming the Tennessee Clinic
Defendants

**NOTICE OF SERVICE OF AMERIDOSE LLC'S RESPONSES TO SAINT
THOMAS ENTITIES' SECOND SET OF REQUESTS FOR PRODUCTION**

Defendant Ameridose LLC gives notice to the Court and to all parties that it has served its written Responses to Saint Thomas Entities' Second Set of Requests for Production. Defendant Ameridose LLC attaches as a collective exhibit to this Notice its Responses to the discovery so as to ensure that all parties in the MDL are served.

Respectfully submitted,

/s/ Matthew P. Moriarty

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CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing has been filed with the Clerk of the Court on June 1, 2015 using the ECF system that sent notification of this filing to all ECF-registered counsel of record via e-mail generated by the Court's ECF system.

/s/ Matthew P. Moriarty

Attorney for Defendant Ameridose LLC

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION,)
MDL No. 2419)
Dkt. No 1:13-md-2419 (RWZ))

THIS DOCUMENT RELATES TO:)
All Suits Against the Saint Thomas Entities)

**AMERIDOSE LLC'S RESPONSES TO SAINT THOMAS ENTITIES' SECOND SET
REQUESTS FOR PRODUCTION**

Defendant Ameridose LLC (“Ameridose”), through its counsel and pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, responds as follows to Saint Thomas Entities’ Second Set of Requests for Production:

PRELIMINARY STATEMENT AND OBJECTIONS

Ameridose objects to Saint Thomas Entities’ Second Set of Requests for Production (“Requests”) on the grounds they are overbroad, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Ameridose further objects to these Requests because they are duplicative of Saint Thomas Entities’ First Set of Requests for Production, which Ameridose responded to on April 8, 2015.

Ameridose is, for purposes of these Responses and as described in this Court's orders, an "Affiliated Defendant," "Related Settling Party," or "Insider Settling Party." Judge Zobel entered an Order on October 9, 2014 staying the MDL proceedings and limiting discovery with respect to NECC Insiders and Related Settling Parties. See NECC MDL Doc. 1482. Pursuant to that Order and the Plan Support and Funding Agreement referenced therein (NECC MDL Doc. 1106-

1), discovery is permitted against Ameridose LLC “only to the extent the discovery is relevant to the prosecution, or defense, of claims against defendants other than the Estate Parties or the Insider Settling Parties.” NECC MDL Doc. 1482.

Saint Thomas Entities seek documents and information from Ameridose in an attempt to establish comparative fault of Ameridose for the manufacturing, compounding, testing, and/or distribution of methylprednisolone acetate (“MPA”), which is the only drug at issue in this litigation. Tennessee product liability law (as defined in Tenn. Code Ann. §29-28-102 (6)) requires that a product liability action based on the doctrine of strict liability in tort and arising from a buyer’s use of an allegedly defective and therefore unreasonably dangerous product, may only be commenced or maintained against the seller of that product where the seller is also the manufacturer of the product or the manufacturer of the defective part of the product. Tenn. Code Ann. §29-28-102(6). Ameridose never compounded, manufactured, tested or distributed MPA at any time; the MPA at issue in this litigation is not an Ameridose product. Ameridose cannot be held liable or considered at fault under Tennessee products liability law. *See e.g., Owens v. Truckstops of America, Inc., et al.*, 915 S.W.2d 420, 433 (Tenn. 1996).

Although NECC and Ameridose were located at the same address from 2006 through early-2009, the companies never shared the same physical space. Since 2009, more than three years before NECC compounded and distributed the contaminated MPA at issue in this litigation, the two companies conducted their respective business operations at separate locations.

Plaintiffs’ Second Amended Master Complaint contains no allegations that Ameridose manufactured, compounded, tested, or distributed MPA, or that any plaintiff ingested and/or was harmed by an Ameridose product. *See* NECC MDL Doc. No. 1719 (Pls.’ 2d Am. Compl., filed

Mar. 6, 2015). Plaintiffs' claims only refer to "NECC contaminated drugs" or drugs "purchased" and "provided to" plaintiffs. *Id.* As to the Clinic Defendants, plaintiffs allege only the following claims: negligence and gross negligence; violation of state consumer protection statutes; failure to warn; Tennessee products liability claims; agency; civil conspiracy; and wrongful death. *See* NECC MDL Doc. 1719. Civil conspiracy, strict liability, and negligence claims are asserted against Saint Thomas Entities in various complaints filed by individual Tennessee plaintiffs. *See e.g.*, NECC MDL Doc. 893, 894 (Saint Thomas Entities' Motion to Dismiss). Saint Thomas Entities fail to demonstrate that plaintiffs assert any claim or that they assert any defense that triggers the exception to the discovery stay. In fact, Saint Thomas Entities never even purchased or injected MPA from NECC. *See* NECC MDL Doc. 1879, 1880 (Ameridose's Motion and Memorandum in Support of Motion to Quash and for Protective Order). Because none of the claims alleged by Plaintiffs and/or against Saint Thomas Entities relate to or implicate Ameridose, there can be no exception to the stay of discovery. *See* NECC MDL Doc. 1482, 1879, 1880.

Furthermore, Saint Thomas Entities' Requests are unreasonably duplicative and responses to the same can be obtained from other sources that are more convenient, less burdensome, and less expensive than from Ameridose. *See* Fed. R. Civ. P. 26(b)(2)(C)(i). Saint Thomas Entities' Requests are also duplicative of their First Set of Requests for Production, to which Ameridose responded on or about April 8, 2015. Many of the Requests propounded on Ameridose in this Second Set are the same or substantially similar to the First Set of Requests.

As Saint Thomas Entities are well aware, discovery in this litigation has been stayed for well over a year and the settlement agreement to which Ameridose LLC is a party is nearly finalized. Ameridose collected documents at the outset of this litigation pursuant to one or more

Litigation Document Holds but has not processed many of the collected documents because of the discovery stay and the lengthy settlement negotiations. For these reasons, Ameridose's ability to respond to Saint Thomas Entities' Requests that are within the scope of the Court's October 9, 2014 Order is limited.

Ameridose responds to these Requests within the parameters of this Court's October 9, 2014 Order and based on counsel for Ameridose's knowledge, information, and belief at this time. Ameridose adopts and incorporates its Motion for Protective Order and to Quash, filed on May 22, 2015 as NECC MDL Doc. 1879, 1880.

RESPONSES TO REQUESTS FOR PRODUCTION

REQUEST FOR PRODUCTION NO. 1: All documents referring or relating to the compounding or manufacture of MPA by NECC.

RESPONSE: Ameridose objects to this Request on the grounds it is overly broad, unduly burdensome, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds it is duplicative or cumulative in that STE propounded the same or substantially similar Request on Ameridose in its First Set of Requests for Production, to which Ameridose responded on or about April 8, 2015. *See* Ameridose's Resp. to STE's 1st RFPs, No. 7. Ameridose further objects to this Request in that Ameridose never manufactured, compounded, tested, or distributed MPA at any time. Ameridose further objects to this Request on the grounds it cannot speak to the business operations of NECC.

REQUEST FOR PRODUCTION NO. 2: All documents referring or relating to the contamination of any NECC cleanroom.

RESPONSE: Ameridose objects to this Request on the grounds it is overly broad, unduly burdensome, irrelevant, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds it is duplicative or cumulative in that the documents or information requested can be obtained from some other source that is more convenient, less burdensome, or less expensive. Ameridose further objects to this Request on the grounds it is not directed to Ameridose. Ameridose further objects to Saint Thomas Entities' definition of "NECC cleanroom" as overly broad in that Ameridose had its own cleanrooms in

which it manufactured or compounded its own products and cannot speak to the business operations of NECC. Subject to and without waiving its objections, Ameridose further states that it operated and maintained its own cleanrooms.

REQUEST FOR PRODUCTION NO. 3: All documents referring or relating to the contamination of any product compounded or manufactured in an NECC cleanroom.

RESPONSE: Ameridose objects to this Request on the grounds it is overly broad, unduly burdensome, irrelevant, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds it is duplicative or cumulative in that STE propounded the same or substantially similar Request on Ameridose in its First Set of Requests for Production, to which Ameridose responded on or about April 8, 2015. *See Ameridose's Resp. to STE's 1st RFPs, Nos. 16-20.* Ameridose further objects to Saint Thomas Entities' definition of "NECC cleanroom" as overly broad in that Ameridose had its own cleanrooms in which it manufactured or compounded its own products and cannot speak to the business operations of NECC. Subject to and without waiving its objections, Ameridose operated and maintained its own cleanrooms.

REQUEST FOR PRODUCTION NO. 4: All documents referring or relating to any recall(s) of any product compounded or manufactured in an NECC cleanroom.

RESPONSE: Ameridose objects to this Request on the grounds it is overly broad, unduly burdensome, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds it is duplicative or cumulative in that the documents or information can be obtained from some other source that is more convenient, less burdensome, or less expensive. Ameridose further objects to Saint Thomas Entities' definition of "NECC cleanroom" as overly broad in that Ameridose had its own cleanrooms in which it manufactured or compounded its own products and cannot speak to the business operations of NECC. Subject to and waiving these objections, Ameridose states that the Ameridose products voluntarily recalled in October 2012 were compounded or manufactured in Ameridose's Westborough, MA facility.

REQUEST FOR PRODUCTION NO. 5: The personnel files for Barry Cadden, Lisa Conigliaro Cadden, Greg Conigliaro, Doug Conigliaro, and Glenn Chin.

RESPONSE: Ameridose objects to this Request on the grounds it is overly broad, unduly burdensome, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds it is duplicative or cumulative in that the

documents or information can be obtained from some other source that is more convenient, less burdensome, or less expensive. Ameridose further objects to this Request on the grounds that, to the extent Ameridose has any of the requested personnel files, they are irrelevant. *See also* Ameridose's Motion and Memorandum in Support of its Motion for Protective Order, NECC MDL Doc. 1879, 1880; Invoking Defendants' Motion to Quash and for Protective Order, NECC MDL Doc. 1823.

REQUEST FOR PRODUCTION NO. 6: All correspondence involving Barry Cadden, Lisa Conigliaro Cadden, Greg Conigliaro, Carla Conigliaro, Doug Conigliaro, or Glenn Chin referring or relating to the following.

1. The compounding or manufacture of MPA;
2. Results of sterility, endotoxin, fungal, or potency testing on MPA;
3. Patient-specific prescriptions or the use of patient lists in connection with orders for pharmaceuticals or products used in the compounding or manufacturing of pharmaceuticals at the NECC facility;
4. Problems or concerns related to the contamination of any NECC cleanroom;
5. Policies and procedures relating to the compounding of drugs in accordance with USP 797;
6. The failure of any product compounded or manufactured by NECC or Ameridose to meet USP standards and/or guidelines;
7. The use of unlicensed pharmacists or technicians to compound medications;
8. The use of expired or expiring ingredients in any product compounded or manufactured by NECC or Ameridose; or
9. The outbreak of fungal meningitis or contamination of MPA that occurred in the Fall 2012, which ultimately led to the closing of NECC and Ameridose.

RESPONSE: Ameridose objects to this Request, and each subpart (1) through (9), on the grounds it is overly broad, unduly burdensome, irrelevant, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds it is duplicative or cumulative in that STE propounded the same or substantially similar Request on Ameridose in its First Set of Requests for Production, to which Ameridose responded on or about April 8, 2015. *See* Ameridose's Resp. to STE's 1st RFPs, Nos. 7, 9, 25, 30, 31. Ameridose further objects that this Request is irrelevant in that the only drug at issue in this litigation is MPA, which Ameridose never

manufactured, compounded, tested, or distributed at any time. Ameridose further objects to Saint Thomas Entities' definition of "NECC cleanroom" as overly broad in that Ameridose had its own cleanrooms in which it manufactured or compounded its own products and cannot speak to the business operations of NECC.

REQUEST FOR PRODUCTION NO. 7: All documents referring or relating to site visits or inspections at the NECC facility conducted by customers of NECC or Ameridose from 2006 to October of 2012.

RESPONSE: Ameridose objects to this Request on the grounds it is overly broad, unduly burdensome, irrelevant, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds it cannot speak to the business operations of NECC or its customers. Subject to and without waiving its objections, Ameridose states it does not have knowledge of site visits to or inspections of NECC's facilities. Ameridose conducted its business operations out of its own facility within a shared building in Framingham, MA between 2006 and early-2009. In early-2009, Ameridose moved its operations to Westborough, MA.

REQUEST FOR PRODUCTION NO. 8: Copies of Quarterly Assurance Report Cards for all quarters from 2009 to October of 2012.

RESPONSE: Ameridose objects to this Request on the grounds it is overly broad, unduly burdensome, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds it is irrelevant in that the only drug at issue in this litigation is MPA, which Ameridose never manufactured, compounded, tested, or distributed at any time. Ameridose further objects to this Request on the grounds it cannot speak to the business operations of NECC.

REQUEST FOR PRODUCTION NO. 9: All documents referring or relating to drugs compounded by NECC or Ameridose that failed any inspection or test.

RESPONSE: Ameridose objects to this Request on the grounds it is overly broad, unduly burdensome, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds it is duplicative or cumulative in that STE propounded the same or substantially similar Request on Ameridose in its First Set of Requests for Production, to which Ameridose responded on or about April 8, 2015. See Ameridose's Resp. to STE's 1st RFPs, No. 8. Ameridose further objects to this Request on the grounds it is irrelevant in that the only drug at issue in this litigation is MPA, which Ameridose never manufactured, compounded, tested, or

distributed at any time. Ameridose further objects to this Request on the grounds it cannot speak to the business operations of NECC.

REQUEST FOR PRODUCTION NO. 10: All documents referring or relating to the design, construction, or manufacture of the NECC cleanrooms.

RESPONSE: Ameridose objects to this Request on the grounds it is overly broad, unduly burdensome, irrelevant, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds it is duplicative or cumulative in that STE propounded the same or substantially similar Request on Ameridose in its First Set of Requests for Production, to which Ameridose responded on or about April 8, 2015. See Ameridose's Resp. to STE's 1st RFPs, No. 9. Ameridose further objects to Saint Thomas Entities' definition of "NECC cleanroom" as overly broad in that Ameridose had its own cleanrooms in which it manufactured or compounded its own products and cannot speak to the business operations of NECC. Subject to and without waiving its objections, Ameridose states it did not correspond with anyone about the design of cleanrooms constructed or manufactured for NECC.

REQUEST FOR PRODUCTION NO. 11: All documents referring or relating to the installation of the NECC cleanrooms.

RESPONSE: Ameridose objects to this Request on the grounds it is overly broad, unduly burdensome, irrelevant, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds it is duplicative or cumulative in that STE propounded the same or substantially similar Request on Ameridose in its First Set of Requests for Production, to which Ameridose responded on or about April 8, 2015. See Ameridose's Resp. to STE's 1st RFPs, No. 9. Ameridose further objects to Saint Thomas Entities' definition of "NECC cleanroom" as overly broad in that Ameridose had its own cleanrooms in which it manufactured or compounded its own products and cannot speak to the business operations of NECC. Subject to and without waiving its objections, Ameridose states it did not correspond with anyone about cleanrooms installed for NECC.

REQUEST FOR PRODUCTION NO. 12: All documents referring or relating to the certification or inspection of the NECC cleanrooms.

RESPONSE: Ameridose objects to this Request on the grounds it is overly broad, unduly burdensome, irrelevant, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds it is duplicative or

cumulative in that STE propounded the same or substantially similar Request on Ameridose in its First Set of Requests for Production, to which Ameridose responded on or about April 8, 2015. *See* Ameridose's Resp. to STE's 1st RFPs, No. 9. Ameridose further objects to Saint Thomas Entities' definition of "NECC cleanroom" as overly broad in that Ameridose had its own cleanrooms in which it manufactured or compounded its own products and cannot speak to the business operations of NECC. Subject to and without waiving its objections, Ameridose states it did not correspond with anyone about cleanrooms certified and inspected for NECC.

REQUEST FOR PRODUCTION NO. 13: All correspondence with any employee of Liberty Industries, Inc. from January of 2005 to October of 2012.

RESPONSE: Ameridose objects to this Request on the grounds it is overly broad, unduly burdensome, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds it is duplicative or cumulative in that the documents or information requested can be obtained from some other source that is more convenient, less burdensome, or less expensive. Ameridose further objects to this Request on the grounds it is irrelevant and not directed to Ameridose, in that the only drug at issue in this litigation is MPA, which Ameridose never manufactured, compounded, tested, or distributed at any time. Subject to and without waiving its objections, Ameridose states that the company was not formed until February 2006. Ameridose further states that any correspondence between it and any employee of Liberty Industries, Inc. related to Ameridose's operations, which are not at issue in this litigation.

REQUEST FOR PRODUCTION NO. 14: All of NECC's and Ameridose's standard operating procedures or other internal policies or procedures related to:

1. Compounding, manufacture, or production of sterile medications, including but not limited to MPA;
2. Ordering pharmaceuticals, chemicals, or other products used in the compounding or manufacture of MPA;
3. Maintaining sterility of the NECC cleanrooms and NECC facility; or
4. Marketing MPA to potential customers.

RESPONSE: Ameridose objects to this Request, and each subpart (1) through (4), on the grounds it is overly broad, unduly burdensome, irrelevant, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds

it is duplicative or cumulative in that Saint Thomas Entities propounded the same or substantially similar Request on Ameridose in its First Set of Requests for Production, to which Ameridose responded on or about April 8, 2015. *See* Ameridose's Resp. to STE's 1st RFPs, No. 7. Ameridose further objects to Saint Thomas Entities' definition of "NECC cleanroom" as overly broad in that Ameridose had its own cleanrooms in which it manufactured or compounded its own products and cannot speak to the business operations of NECC. Ameridose further objects to this Request on the grounds it is irrelevant in that the only drug at issue in this litigation is MPA, which Ameridose never manufactured, compounded, tested or distributed at any time.

REQUEST FOR PRODUCTION NO. 15: All documents relating to UniFirst

Corporation and services provided by it at any NECC cleanroom.

RESPONSE: Ameridose objects to this Request on the grounds it is overly broad, unduly burdensome, irrelevant, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to this Request on the grounds it is duplicative or cumulative in that STE propounded the same or substantially similar Request on Ameridose in its First Set of Requests for Production, to which Ameridose responded on or about April 8, 2015. *See* Ameridose's Resp. to STE's 1st RFPs, No. 25. Ameridose further objects to Saint Thomas Entities' definition of "NECC cleanroom" as overly broad in that Ameridose had its own cleanrooms in which it manufactured or compounded its own products and cannot speak to the business operations of NECC. Ameridose further objects to this Request on the grounds it is duplicative or cumulative in that the documents or information requested can be obtained from some other source that is more convenient, less burdensome, or less expensive. Subject to and without waiving its objections, Ameridose states that after a reasonable search of its available documents, it did not identify documents referring or relating to cleaning services UniFirst provided at Ameridose's facilities.

REQUEST FOR PRODUCTION NO. 16: All documents relating to cause or

potential cause of MPA contamination at any NECC cleanroom.

RESPONSE: Ameridose objects to this Request on the grounds it is overly broad, unduly burdensome, irrelevant, and not within the permissible scope of discovery outlined by this Court in its October 9, 2014 Order (NECC MDL Doc. 1482). Ameridose further objects to Saint Thomas Entities' definition of "NECC cleanroom" as overly broad in that Ameridose had its own cleanrooms in which it manufactured or compounded its own products and cannot speak to the business operations of NECC. Ameridose further objects to this Request on the grounds it is duplicative or cumulative in that the documents or information requested can be obtained from some other source that is more convenient, less burdensome, or less expensive. Ameridose further objects to this Request on the grounds it is not

directed to Ameridose, in that Ameridose did not manufacture, compound, test, or distribute MPA at any time.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 27, 2015, a copy of the foregoing AMERIDOSE, LLC'S RESPONSES TO SAINT THOMAS ENTITIES' SECOND SET OF REQUESTS FOR PRODUCTION was filed electronically as an attachment to a Notice of Service. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

s/ Matthew P. Moriarty

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